

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the following remarks.

Claim Status

Claims 1-20 were presented in the originally filed application. Claims 14-20 are withdrawn. Claims 1-13 are pending. Claim 13 is amended. No new matter was added.

Discussion

Claim 13 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 also stands rejected under and 35 U.S.C. 101 because the claimed recitation of use, without setting forth any steps involved in the process, results in an improper definition of a process. Applicant traverses.

Applicant has amended claim 13 to more closely resemble the language used in claim 1 of the instant application. Claim 13 now properly sets forth steps involved in a method for cultivating microorganisms of the order *Thraustochytriales*. In light of the amendment of claim 13, applicant requests that the

Examiner withdraw the rejection of claim 13 under both §112 and §101 and the claim be allowed.

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,582,941 (Yokochi), U.S. Patent No. 6,509,178 (Tanaka), EP 0 113 183 (Carson), and Bajpai. Applicant traverses.

The combination of Yokochi, Tanaka, Carson, and Bajpai fail to establish a *prima facie* case of obviousness. MPEP §2143 "Basic Requirements of a *Prima Facie* Case of Obviousness" states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations.

Regarding the third criterion, the court has stated that "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicant contends that none of the prior art references, Yokochi, Tanaka, Carson, and Bajpai, alone or in combination,

teach, suggest, or provide a motivation for making an article of manufacture with all of the claim elements from independent claims 1 and 13. More specifically, Applicant contends that none of the prior art references, alone or in combination, teach, suggest or provide a motivation for a method for cultivating microorganisms of the order *Thraustochytriales*, characterized in that the microorganisms are cultivated in a fermentation medium containing CaCO_3 as an essential (or exclusive) means for pH value stabilization, where content of CaCO_3 , in the fermentation medium is 3 to 15 g/l.

In sum, the rejection goes like this: Yokochi is cited for the purpose of disclosing cultivation of Schizochytrium Genus SR21 for the production of DHA and DPA. Yokochi, Column 18, Lines 14-23. As noted by the Examiner, Yokochi makes no reference to the use of calcium carbonate as a material for the adjustment of pH levels in the fermentation medium. On the contrary, Yokochi clearly states that after preparing the medium, "the pH is adjusted to the range between 4.0 and 6.5 using a suitable acid or base, and the medium is sterilized by autoclaving." Yokochi, Column 10, Line 64 - Column 11, Line 1. As indicated by the Examiner, Yokochi contains absolutely no details regarding the use of calcium carbonate as a material for the adjustment of pH levels in a fermentation medium, what

quantity of calcium carbonate shall be included, or what benefits are obtained by the use of calcium carbonate in the production of DHA or DPA from microorganisms of the order *Thraustochytriales*.

The Examiner then cites Tanaka for the purpose of disclosing cultivation of *Ulenia* sp. strain SAM 2179 for the production of DHA and DPA. Tanaka, Column 2, Lines 63-65. As noted by the Examiner, Tanaka makes no reference to the use of calcium carbonate as a material for the adjustment of pH levels in the fermentation medium. On the contrary, Tanaka, like Yokochi, clearly states that after preparing the medium, the pH is adjusted "using asuitable acid or base, and the medium is sterilized by autoclaving." Tanaka, Column 4, Lines 50-54. Again, as indicated by the Examiner, Tanaka contains absolutely no details regarding the use of calcium carbonate as a material for the adjustment of pH levels in a fermentation medium, what quantity of calcium carbonate shall be included, or what benefits are obtained by the use of calcium carbonate in the production of DHA or DPA from microorganisms of the order *Thraustochytriales*.

The Examiner then cites Carson which discloses the use of calcium carbonate in the liquid phase of a fermentation mixture.

Carson, Page 9, Lines 7-11. However, the Examiner's reliance on Carson is misplaced. Carson is directed to a method for fermenting alcohol, and more specifically, "to produce substantially flavourless and colourless alcohol bases for use in making mixer drinks." Carson, Page 1, Lines 3-6. This is in stark contrast to the instant invention which discloses the fermentation of marine microorganisms for the production of polyunsaturated fatty acids, not the fermentation of yeast for the production of alcohol. Additionally, Carson clearly states that, "the present invention provides a method for fermenting an aqueous sugar solution using a yeast..." Carson, Page 3, Lines 1-2. The instant invention does not use yeast, and in fact only calls for the use of yeast extract, which, as is known in the art, is no longer capable of fermenting sugars.

Carson makes no allusion to the production of polyunsaturated fatty acids and, more specifically, to the disposition of pH stabilizing means in the production of DHA or DPA from the fermentation of marine organisms as stated in the specification of the instant application. "[U]ntil the present invention, no known fermentation process was available for producing n-3 fatty acids in microorganisms of the order *Thraustochytriales* using a medium pH-stabilized with calcium carbonate, where it was possible to dispense with further pH

value stabilizing means." Specification, Page 6, Lines 6-9.

Clearly, the Examiner's reliance on Carson is misplaced.

The Examiner also cites the reference by Bajpai as disclosing the cultivation of *Thraustochytrium aureum*, in a culture medium containing calcium carbonate. The Examiner's reliance on Bajpai is again misplaced. Bajpai makes no allusion to the use of CaCO_3 as an essential means for pH value stabilization in the production of DHA or DPA from microorganisms of the order *Thraustochytriales*. The Examiner is correct in that Bajpai discloses a culture medium containing 0.1 g/L of calcium carbonate. Bajpai, Materials and Methods. However, the instant invention calls for 3 to 15 g/L of calcium carbonate as an essential means for pH value stabilization for optimum production of DHA or DPA from microorganisms of the order *Thraustochytriales*. That is 30 to 150 times the amount disclosed in Bajpai, and would not lead one skilled in the art down the path of using calcium carbonate as an essential (or exclusive) means for pH value stabilization.

The Examiner makes the assertion that the combination of Yokochi, Tanaka, Carson, and Bajpai would have suggested to one having ordinary skill in the art that to use calcium carbonate as pH controlling material during cultivation of microorganisms

belonging to the order *Thraustochytriales* with a reasonable expectation of success. Applicant must respectfully disagree. None of the above mentioned references make any allusion to the use of CaCO_3 as an essential (or exclusive) means for pH value stabilization in the production of DHA or DPA from microorganisms of the order *Thraustochytriales*. Both Yokochi and Tanaka explicitly teach the use of a conventional acid or base as the means of pH stabilization, whose use is one of the problems that the instant invention seeks to remedy. Specification, Page 2, Line 29 - Page 3, Line 21. Carson makes use of CaCO_3 in the fermentation of alcohol in order to remedy problems associated with the flavor of the final distilled product. Carson, Page 1, Lines 3-6. While Bajpai only makes a passing reference as to the use of CaCO_3 without any explanation as to what benefits are obtained by the use of calcium carbonate in the production of DHA or DPA from microorganisms of the order *Thraustochytriales*.

This is in stark contrast to the instant invention which sought to provide a novel, simple, and economic cultivating method for marine microorganisms. Page 3, Lines 18-21. More specifically, the instant invention discloses an advantageous method for cultivating microorganisms of the order

Thraustochytriales through the use of calcium carbonate as an essential means for pH value stabilization.

The high efficacy of calcium carbonate as buffer for cultivating microorganisms of the order *Thraustochytriales* is surprising, since the carbon dioxide formed only has limited solubility in water, which leads to a decreasing buffer capacity during fermentation.

Surprisingly, not only the fermentation up to the complete glucose consumption was possible, but, in addition to that, the proportion of PUFA in the biomass significantly increased when using the calcium carbonate stabilized medium according to the invention. Even more surprising is that the glucose utilization and, related to that, the PUFA production is accelerated, thereby leading to an increased space-time yield.

Page 5, Line 28 - Page 6, Line 5. The dramatic and unexpected increase in glucose consumption, and increase in polyunsaturated fatty acid biomass is illustrated in Tables 1-5, pages 11-19 of the instant application. (Glucose consumption of 108.4 g/L - 150 g/L and biomass of 52.32 g/L - 67.8 g/L). As previously stated, "[U]ntil the present invention, no known fermentation process was available for producing n-3 fatty acids in microorganisms of the order *Thraustochytriales* using a medium pH-stabilized with calcium carbonate, where it was possible to dispense with further pH value stabilizing means." Page 6, Lines 7-9.

The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above, it is clear that Yokochi, Tanaka, Carson, and Bajpai fail to teach or suggest all the limitations of Applicant's claims.

The U.S. Supreme Court recently held that rigid and mandatory application of the "teaching-suggestion-motivation," or TSM, test is incompatible with its precedents. *KSR Int'l Co. v. Teleflex, Inc.* 127 S.Ct 1727, 1741 (2007). The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*

The Court held that the TSM test must be applied flexibly, and take into account a number of factors "in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed." *Id.* at 1740-41. Despite this flexibility, however, the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does." *Id.* "To facilitate review, this analysis should be made explicit." *Id.*

The obviousness rationale addressed in *KSR* was premised on combining elements known in the prior art. *Id.* at 1738-39. The *KSR* Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed." *Id.* at 1741.

In the same way, when the prior art teaches away from the claimed solution, obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way

that would result in the claimed composition. See also *Ex parte Thomas J. Whalen II, et al*, BPAI 2007-4423 (2008).

Based on *KSR v. Teleflex, Inc.* 127 S.Ct. 1727, 167 L.Ed2d 705, 2007 U.S. Lexis 4745 (2007), the obviousness question may be broken down to: Is the invention predictable based upon the prior art? *Id.* at 1740, 721.

Simply, the answer to that question is "no." Hindsight reconstruction is not permitted as the Federal Circuit has repeatedly warned that the requisite motivation to modify a reference must come from the prior art, not Applicant's specification. See *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-32 (Fed. Cir. 1988) ("there must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure.") Using an Applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated piece of the prior art contravenes the statutory mandate of section 103 of judging obviousness at the point in time when the invention was made. See *Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Only hindsight reconstruction based upon the instant specification would lead the Examiner to the conclusion that the claims in the instant application are rejected under §103 as unpatentable over Yokochi, Tanaka, Carson, and Bajpai. Accordingly, the instant rejection of independent claims 1 and 13 must be removed.

In reference to claims 2-12, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Thus, claims 2-12 are not unpatentable over Yokochi, Tanaka, Carson, and Bajpai and should be allowed.

Reconsideration and allowance of this application is respectfully requested.

Respectfully submitted,



Blake E. Vande Garde
Attorney for Applicant
Registration No. 38,906

Customer No. 29494
Hammer & Associates, P.C.
3125 Springbank Lane
Suite G
Charlotte, NC 28226
Telephone: 704-927-0400
Facsimile: 704-927-0485
H:\2024\005\Amendment110308.doc